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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,906	05/01/2006	Hirotaka Haro	284133US0XPCT	4406

22850 7590 06/19/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,906	HARO ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☒ Claim(s) *6-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *30 Dec 2005 and 8 May 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are presented and represent all claims under consideration.

Information Disclosure Statement

Two Information Disclosure Statements (IDS) filed 30 December 2005 and 8 May 2006 are acknowledged and have been reviewed.

Claim Objections

Claims 6-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, and/or, cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5 and 7 of copending Application No. 12/027,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5 of the instant application and claims 1, 2, 5 and 7 are directed to a self-crosslinking, hyaluronic acid material which may be in the form of a suspension. Claim 7 of the conflicting application teaches that the medical material maybe in the form of a pharmaceutically acceptable dispersion with hyaluronic acid. An artisan of ordinary skill in the pharmaceutical art would be able to practice the instant invention with a reasonable expectation of success under the guidance of the '365 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 6,635,267, over claims 1, 2, 7, 14, 15 and 26 of U.S. Patent No. 6,638,538, over claim 10 of U.S. Patent No. 6,387,413, and over claims 1 and 8 of U.S. Patent No. 7,014,860. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the different claim sets are directed to a self-crosslinking, hyaluronic acid material which may be in the form of a film or sponge.

The '267 patent teaches a gel composition which is formed from self-crosslinked (e.g. autocrosslinked) hyaluronic acid (claims 1 and 6).

The '538 patent teaches a polymerized composition of hyaluronic acid and carboxymethylcellulose wherein the composition does not require the use of cross-linking agents or chemical modifying agents, which inherently implies that the compounds are self-crosslinking (claims 1 and 2). Claims 14 and teach the composition as being an adhesion preventative and a wound dressing, respectively. Claim 26 teaches the composition in the form of a film-, sponge-, or suspension- (e.g. pulverized) form.

Claim 10 of the '413 patent teaches a biomedical material in the form of a film or a sponge containing hyaluronic acid gel wherein said gel has not been subjected to chemical cross-linking or chemical modification by a compound other than hyaluronic acid (e.g. auto- or self-crosslinking).

Claims 1 and 8 teach an autocrosslinked hyaluronic acid gel which does not contain any other cross-linking agents.

An artisan of ordinary skill in the pharmaceutical art would be able to practice the instant invention with a reasonable expectation of success under the guidance of any of the aforementioned patents.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "wherein the time the dissolution rate of the cross-linked acid polysaccharide becomes 50% in a phosphate buffered physiological saline (pH 7.4) at 60°C, is at least 15 hours" in lines 2-5 of the claim. There is insufficient antecedent basis for this limitation in the claim. The above mentioned limitation is also deemed by the Examiner, for the purposes of examination on the merits, to be a functional limitation which does not further define the composition (see MPEP § 2173.05(h)). Furthermore, previously unappreciated or undiscovered properties of compositions which are known in the art, such as the aforementioned, does not render the old composition patentably new and thus the claiming of a property which is inherently present in the prior art does not necessarily make the claim patentable (MPEP §2112).

Claim 3 recites the limitation "the acid polysaccharide" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 4 and 5 recite the limitation "the cross-linking structure" in line 2 of both claims. There are insufficient antecedent bases for this limitation in the claims. Furthermore, since it is not clear which "cross-linking structure" is being referred to within the crosslinked acid polysaccharide composition, it follows that the claimed "cross-linking structure" may broadly and reasonably be interpreted as referring to any linking structure within the polyacid molecule, including the ester bonds, such as those that occur naturally in both hyaluronic acid (see *Merck Index, 9th Ed.*) and carboxymethylcellulose.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyoshi et al. (USPN 6,635,267). It should be noted that the '267 patent is the English translation of WO 00/27405, which was published in Japanese on 18 May 2000.

The instant claims 1, 2 and 4 are directed to an adhesion-inhibiting material which contains a cross-linked acid polysaccharide. The limitations of claim 1 such as "for a spine/spinal cord surgery" and "to be used for reducing the degree of adhesion or for inhibiting adhesion caused by a spine/spinal cord surgery" are both considered to be limitations of intended use, which per MPEP §2114, hold no patentable weight with regards to the instantly claimed composition. Claim 3 further limits the acid polysaccharide to hyaluronic acid (HA) and/or carboxymethylcellulose (CMC). As discussed earlier, the ester bond as a limitation to the cross-linking structure is inherent limitation since it naturally occurs within the chemical structure of both HA and CMC. Claim 5 recites that the ester bond of claim 4 is a self-crosslinking bond.

The teachings of Miyoshi et al. are discussed above. The gel composition of the instant invention is further defined as being filmy or spongy (col. 4, lines 42-46).

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. (USPN 6,638,538). It should be noted that the '538 patent is the English translation of WO 00/49084, which was published in Japanese on 24 August 2000.

The instant claims are directed to a self-crosslinking acid polysaccharide sponge, film or suspension material, described above.

The teachings of claims 1, 2, 7, 14, 15 and 26 of Hashimoto et al. are discussed above.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. (USPN 6,387,413). It should be noted that the '413 patent is the English translation of WO 99/10385, which was published in Japanese on 4 March 1999 and is further noted as having been submitted for consideration by Applicants.

The instant claims are directed to a self-crosslinking acid polysaccharide sponge, film or suspension material, described above.

The teachings of claim 10 of Miyata et al. are discussed above. The composition of claims 5 and 7 further teach the material as being an adhesion preventive.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawata et al. (USPN 7,014,860). It should be noted that the '860 patent is the English translation of WO 01/57093, which was published in Japanese on 9 August 2001.

The instant claims are directed to a self-crosslinking acid polysaccharide sponge, film or suspension material, described above.

The teachings of claims 1 and 8 of Kawata et al. are discussed above. Kawata further defines the hyaluronic acid gel formed in the claims and Examples as taking on a film or sponge form (col. 8, lines 59-65).

No claims allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615